

Charles M. Lizza
William C. Baton
Saul Ewing LLP
One Riverfront Plaza, Suite 1520
Newark, NJ 07102-5426
(973) 286-6700
clizza@saul.com

Attorneys for Plaintiffs
Jazz Pharmaceuticals, Inc. and
Jazz Pharmaceuticals Ireland Limited

James E. Cecchi
Melissa E. Flax
Carella, Byrne, Cecchi, Olstein, Brody &
Agnello, P.C.
5 Becker Farm Road
Roseland, New Jersey 07068-1739
(973) 994-1700
JCecchi@carellabyrne.com

Attorneys for Defendants Lupin Limited, Lupin
Pharmaceuticals, Inc. and Lupin Inc.

Paul H. Kochanski
Lerner, David, Littenberg,
Krumholz & Mentlik, LLP
600 South Avenue West
Westfield, NJ 07090
(908) 654-5000
pkochanski@ldlkm.com

Attorneys for Defendant
Amneal Pharmaceuticals, LLC

Liza M. Walsh
Tricia O'Reilly
Katelyn O'Reilly
WALSH PIZZI O'REILLY
FALANGA LLP
One Riverfront Plaza
1037 Raymond Blvd., 6th Floor
Newark, NJ 07105
(973) 757-1100
lwalsh@walsh.law

Attorneys for Defendant Watson Laboratories,
Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JAZZ PHARMACEUTICALS, INC. and
JAZZ PHARMACEUTICALS IRELAND
LIMITED

Plaintiffs,

v.

AMNEAL PHARMACEUTICALS, LLC, et
al.,

Defendants.

Civil Action No. 13-391 (ES)(JAD)
(Consolidated)

(Filed Electronically)

JOINT CLAIM CONSTRUCTION AND PREHEARING STATEMENT

Plaintiffs Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited (collectively, “Jazz”) and Defendants Amneal Pharmaceuticals, LLC (“Amneal”), Lupin Limited, Lupin Pharmaceuticals, Inc. and Lupin Inc. (collectively, “Lupin”), and Watson Laboratories, Inc. (“Watson”) (collectively, Amneal, Lupin and Watson are referred to herein as “Defendants”)¹ hereby submit their Joint Claim Construction and Prehearing Statement in accordance with L. Pat. R. 4.3.

I. BACKGROUND

This case arises out of Defendants’ filing of Abbreviated New Drug Applications (“ANDA”) with the U.S. Food and Drug Administration (“FDA”), which seek approval to market a generic version of Jazz’s XYREM® product. The active ingredient in XYREM® is sodium oxybate. Jazz alleges, among other things, that Defendants’ ANDA submissions to the FDA constitute infringement of certain claims of U.S. Patent Nos. 6,472,431 (“the ‘431 patent”), 6,780,889 (“the ‘889 patent”), 7,262,219 (“the ‘219 patent”), 7,851,506 (“the ‘506 patent”), 8,263,650 (“the ‘650 patent”), 8,461,203 (“the ‘203 patent”), 8,324,275 (“the ‘275 patent”), 8,859,619 (“the ‘619 patent”), and 8,952,062 (“the ‘062 patent”), (collectively, the “‘431 patent family”), and 8,772,306 (“the ‘306 patent”) and 9,050,302 (“the ‘302 patent”) (collectively, the “‘306 patent family”) owned by Jazz (collectively, “the patents-in-suit”) under 35 U.S.C. § 271(e)(2). Defendants allege, among other things, that the asserted claims are invalid and not infringed.

¹ Defendant Par Pharmaceutical, Inc., against whom only the ‘306 patent is presently asserted (all other patents having been dismissed or stayed in this case) believes that no construction is necessary for any term of that patent, agrees to any agreed-upon constructions of terms in that patent, and does not intend to submit a brief in support of any position regarding construction of any term in that patent.

Pursuant to L. Pat. R. 4.2(a)-(b), on September 9, 2016, the parties exchanged preliminary claim constructions and identified intrinsic as well as extrinsic evidence in support of their proposed preliminary constructions. Pursuant to L. Pat. R. 4.2(c), on September 23, 2016, the parties exchanged intrinsic and extrinsic evidence opposing the other side's proposed constructions. Pursuant to L. Pat. R. 4.2(d), on October 7, 2016, counsel for the parties met and conferred for the purposes of narrowing the issues and preparation of the Joint Claim Construction and Prehearing Statement.

II. CONSTRUCTION OF PATENT TERMS

A. Agreed Upon Claim Constructors

Pursuant to L. Pat. R. 4.3(a), the parties identify the following ten claim terms and constructions upon which Plaintiffs and Defendants agree:

Claim Term, Phrase, Clause	Agreed Construction
“chemically stable” (’431 patent claims 1-7; ’889 patent claim 1; ’219 patent claims 1-4; ’650 patent claims 1-18; ’203 patent claims 1-18)	“Resistant to degradation of GHB into its known or unknown decomposition elements.”
“first container means” (’650 patent claims 17, 18)	“A container distinct from a second and third container.”
“second container means” (’650 patent claims 17, 18)	“A container distinct from a first and third container.”
“delivery vehicles” (’650 patent claims 17, 18)	“An instrument for assisting with the administration of the sodium gammahydroxybutyrate composition to a patient.”
“acid” (’431 patent claims 6, 7; ’889 patent claim 1; ’219 patent, claims 1, 3, 4; ’650 patent, claims 6-10; ’203 patent claims 3, 4, 12, 13; ’619 patent claims 8-12)	“A substance that lowers pH.”

“inorganic acid” (’650 patent, claim 7; ’619 patent, claim 9)	“A substance that does not contain any carbon atoms that lowers pH.”
“resistant to microbial growth” (’431 patent, claim 1; ’889 patent claim 1; ’219 patent, claims 1, 4; ’650 patent, claims 1; ’619 patent, claims 1, 13; ’062 patent, claims 4, 10; ’203 patent, claims 1, 9, 10)	“The formulations meet the criteria set by the Food and Drug Administration and the U.S. Pharmacopeia for products made with aqueous bases or vehicles, which for bacteria means not less than a 1.0 log reduction from the initial count at 14 days, and no increase from 14 days count at 28 days, and for yeast and molds, no increase from the initial calculated count at 14 and 28 days.”
“preservative” (’431 patent, claim 4; ’889 patent, claim 1; ’219 patent, claims 1, 4; ’650 patent claim 1; ’619 patent, claims 18, 20; ’062 patent, claims 4, 10; ’203 patent, claims 1, 9, 10, 16)	“A substance or substances added in addition to the gamma-hydroxybutyrate salt to inhibit chemical change or microbial action.”
“concomitant” (’306 patent, claims 1, 3, 8, 17; ’302 patent, claims 1, 3, 5-8, 11, 13, 19)	“The administration of at least two drugs to a patient either subsequently, simultaneously, or consequently within a time period during which the effects of the first administered drug are still operative in the patient.”
“effective dosage amount” / “therapeutically effective amount” (’306 patent claims 1, 2, 4, 7, 9, 10, 19, 30, 33)	“An amount of a [gamma-hydroxybutyrate (GHB) or a salt thereof] sufficient to treat, ameliorate, or prevent [excessive daytime sleepiness, cataplexy, sleep paralysis, apnea, narcolepsy, sleep time disturbances, hypnagogic hallucinations, sleep arousal, insomnia, or nocturnal myoclonus], or to exhibit a detectable therapeutic, prophylactic, or inhibitory effect.”

B. Disputed Claim Terms

Pursuant to L. Pat. R. 4.3(b), attached hereto as Exhibit A is a series of claim charts identifying the claim terms and phrases in dispute and the parties’ proposed constructions, as well as intrinsic and extrinsic evidence that the parties intend to rely upon either to support their proposed construction or to oppose the other side’s proposed construction.

C. Claim Terms Whose Construction Will Be Most Significant

Pursuant to L. Pat. R. 4.3(c), the parties were unable to agree which terms’ “construction will be most significant to the resolution of the case.” Likewise, the parties were unable to agree which terms’ “construction will be case or claim dispositive or substantially conducive to promoting settlement.”

1. By Jazz:

None of the disputed claims terms below will likely be dispositive to the outcome of this case.

To the extent that the Court construed any terms of the claims of the patents-in-suit in the action *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, Civil Action No. 10-6108 (ES)(MAH) (“the Roxane matter”), those terms should have the same construction in this matter. (See Civil Action No. 10-6108, D.I. 151, 152.) Jazz reserves its right, however, to appeal the Court’s claim constructions in both this matter and in the Roxane matter.

Jazz disagrees with Defendants’ contention that the claim term “third container means” should be subject to “means-plus-function” requirements of 35 U.S.C. § 112, ¶ 6. This claim term does not contain the language associated with means-plus-function claims, and the Patent Office did not interpret this claim term as being subject to § 112, ¶ 6. Jazz further disagrees with Defendants’ contention that this claim term is indefinite.

2. By Defendants:

Defendants believe certain of the claim terms in dispute may be dispositive with respect to Plaintiffs’ allegations that one or more of the Defendants infringe certain claims of the patents-in-suit and/or dispositive with respect to one or more basis for Defendants’ counterclaims of invalidity of certain claims of the patents-in-suit.

Specifically, the claim term “administering” may be dispositive of Plaintiffs’ allegation that Defendants infringe the claims of the ’306 patent and ’302 patent. The ’306 patent and ’302 patent do not define the term “administering.” Defendants’ construction is based on extrinsic evidence and establishes that to “administer” is to “give or apply” in a medical context. Defendants cannot directly infringe the asserted claims of the ’306 patent and ’302 patent because Defendants do not administer their ANDA products and Defendants cannot indirectly infringe because the steps of the asserted methods will not all be performed by a single person or entity. *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111, 2118 (2014).

The claim terms “admixing a salt of gamma hydroxybutyrate with the aqueous medium,” “admixing sequentially” and “the components are admixed simultaneously” may be dispositive of Plaintiffs’ allegations that Defendants infringe claims of the ’203 patent.

The claim term “an aqueous composition comprising a first dose . . . and an aqueous composition comprising a second dose” may be dispositive of Plaintiffs’ allegation that Defendants infringe the claims of the ’506 and ’062 patents.

The claim term “third container means” may be dispositive of Defendants’ counterclaim of invalidity of claims 17 and 18 of the ’650 patent for lacking a corresponding structure. And Defendants cannot infringe an invalid claim. As detailed in Exhibit A, Defendants contend that this is a means-plus-function limitation without sufficient disclosure of corresponding structure in the specification.

Defendants reserve the right to edit or modify the proposed constructions and identification of disputed and agreed-upon terms identified herein, whether collectively or independently.

D. Anticipated Length of Time Necessary for the Claim Construction Hearing

Pursuant to L. Pat. R. 4.3(d), the parties anticipate that the Court will be able to conduct a hearing on the meaning of the disputed terms in less than one day.

E. Identification of Witnesses for the Claim Construction Hearing

Pursuant to L. Pat. R. 4.3(e), the parties do not currently plan to call any witnesses at the claim construction hearing.

Dated: October 11, 2016

Respectfully submitted,

By: s/ Charles M. Lizza

Charles M. Lizza
William C. Baton
SAUL EWING LLP
One Riverfront Plaza, Suite 1520
Newark, New Jersey 07102-5426
(973) 286-6700
clizza@saul.com

OF COUNSEL:

F. Dominic Cerrito
Eric C. Stops
Gabriel P. Brier
QUINN EMANUEL URQUHART
& SULLIVAN LLP
51 Madison Avenue
22nd Floor
New York, New York 10010
(212) 849-7000

Richard G. Greco
RICHARD G. GRECO PC
90 State Street, Suite 700
Albany, New York 12207
(212) 203-7625

*Attorneys for Plaintiffs
Jazz Pharmaceuticals, Inc. and
Jazz Pharmaceuticals Ireland
Limited*

By: s/ Liza M. Walsh

Liza M. Walsh
Tricia O'Reilly
Katelyn O'Reilly
WALSH PIZZI O'REILLY
FALANGA LLP
One Riverfront Plaza
1037 Raymond Blvd., 6th Floor
Newark, NJ 07105
(973) 757-1100

Respectfully submitted,

By: s/ Paul H. Kochanski

Paul H. Kochanski
LERNER, DAVID, LITTBENBERG,
KRUMHOLZ & MENTLIK, LLP
600 South Avenue West
Westfield, New Jersey 07090
(908) 654-5000
pkochanski@ldlkm.com

OF COUNSEL:

Steven A. Maddox
Matthew C. Ruedy
MADDOX EDWARDS, PLLC
1900 K Street NW – Suite 725
Washington, D.C. 20006
(202) 830-0707

*Attorneys for Defendant
Amneal Pharmaceuticals, LLC*

By: s/ Melissa E. Flax

James E. Cecchi
Melissa E. Flax
CARELLA, BYRNE, CECCHI,
OLSTEIN, BRODY & AGNELLO, P.C.
5 Becker Farm Road
Roseland, New Jersey 07068-1739
(973) 994-1700
JCecchi@carellabyrne.com

lwalsh@walsh.law

OF COUNSEL:

Gary E. Hood
Mark T. Deming
POL SINELLI PC
161 N. Clark St. Suite 4200
Chicago, IL 60601
(312) 819-1900
MDeming@Polsinelli.com

*Attorneys for Defendant Watson
Laboratories, Inc.*

OF COUNSEL:

William A. Rakoczy
Paul J. Molino
Deanne M. Mazzochi
Jeff A. Marx
RAKOCZY MOLINO MAZZOCHI
SIWIK LLP
6 West Hubbard Street, Suite 500
Chicago, IL 60654
(312) 527-2157
jmarx@rmmslegal.com

*Attorneys for Defendants Lupin
Limited, Lupin Pharmaceuticals,
Inc. and Lupin Inc.*

EXHIBIT A

Exhibit A**Disputed Claim Terms****'431 PATENT FAMILY**

Term (Patent Claims)	Jazz's Proposed Definition	Jazz's Evidence	Defendants' Proposed Definition	Defendants' Evidence
"third container means" ('650 patent claims 17, 18)	A container distinct from a first and second container.	'650 patent at col. 9:65 to col. 10:42; col. 15:62 to col. 16:37; col. 28:9- 14. '650 patent file history. Jazz may also rely on expert testimony.	Defendants contend that the term "third container means" is a means-plus- function claim within the scope of 35 U.S.C. § 112, ¶6. Function: "third container means capable of retaining a first container means, a second container means, and one or more delivery vehicles capable of administering the pharmaceutical composition to the patient" Defendants contend that the term "third container means" should be construed as a means- plus-function term	35 U.S.C. § 112, ¶6. <u>Intrinsic Evidence</u> '650 patent, col. 9, line 65, to col. 10, line 42; col. 15, line 62, to col. 16, line 37; col. 17, ll. 25-30; col. 18, ll. 3-5; col. 20, ll. 40-44; col. 22, ll. 40-67; col. 23, line 63, to col. 24, line 16; col. 28, ll. 4-25; col. 36, line 66, to col. 37, line 6; col. 71, ll. 3-6 (AMNXYR_000006947- AMNXYR_000006986) '619 patent, col. 9, l. 65 – col. 10, l. 43; col. 15, l. 64 – col. 16, l. 39; col. 17, ll. 28-33; col. 18, ll. 3-6; col. 21, ll. 1-4; col. 23, ll. 1-25; col. 24, ll. 22-42; col. 28, 31-50;

Term (Patent Claims)	Jazz's Proposed Definition	Jazz's Evidence	Defendants' Proposed Definition	Defendants' Evidence
			<p>within the scope of 35 U.S.C. § 112, ¶6. See <i>Altiris, Inc. v. Symantec Corp.</i>, 318 F.3d 1363, 1375 (Fed. Cir. 2003); <i>Biomedino, LLC v. Waters Technologies Corp.</i>, 490 F.3d 946, 950 (Fed. Cir. 2007).</p> <p>This claim requires that the third container means has a function, but gives the means no structure: “third container means capable of retaining a first container means, a second container means, and one or more delivery vehicles capable of administering the pharmaceutical composition to the patient.” The specification fails to provide sufficient disclosure of a structure for the “third container means” making this term, and any claim in which it appears,</p>	<p>col. 37, ll. 38-43; (AMNXYR_0000091091 - AMNXYR_0000091134) ’650 patent file history.</p> <p><u>Extrinsic Evidence</u></p> <p>Remington: The Science and Practice of Pharmacy, 19th Ed. (1995): “A pharmaceutical container has been defined as a device which holds the drug and is, or may be, in direct contact with the preparation. The immediate container is described as that which is in direct contact with the drug at all times.” (AMNXYR_000007747-AMNXYR_000007757)</p> <p>Defendants may rely on expert testimony.</p>

Term (Patent Claims)	Jazz's Proposed Definition	Jazz's Evidence	Defendants' Proposed Definition	Defendants' Evidence
			indefinite: a lack of sufficient disclosure of structure under 35 U.S.C. § 112, ¶6, renders a claim indefinite, and thus not amenable to construction. <i>See In re Aoyama</i> , 656 F.3d 1293, 1298 (Fed. Cir. 2011) (quoting <i>Enzo Biochem, Inc. v. Applera Corp.</i> , 599 F.3d 1325, 1332 (Fed. Cir. 2010) (“If a claim is indefinite, the claim, by definition, cannot be construed.”)).	
“admixing a salt of gamma hydroxybutyrate with the aqueous medium” (’203 patent, claim 1)	No construction necessary.	‘203 patent at col. 8:49 to col. 8:53; col. 8:61 to 8:65; col. 15:44 to 15:47 ‘203 patent file history Jazz may also rely on expert testimony.	“the act of creating a mixture by adding a salt of gamma hydroxybutyrate to an aqueous medium”	<u>Intrinsic Evidence</u> ’203 patent at col. 3, ll. 51-53; col. 4, ll. 16-17; col. 7, ll. 19-22; col. 8, ll. 43-47; col. 8, ll. 49-57; col. 8, ll. 61-65; col. 10, ll. 16-19 Prosecution History of the ’203 patent, 4/13/12 Amendment at 2, 4

Term (Patent Claims)	Jazz's Proposed Definition	Jazz's Evidence	Defendants' Proposed Definition	Defendants' Evidence
				<p><u>Extrinsic Evidence</u></p> <p>NINTH NEW COLLEGIATE DICTIONARY – MERRIAM WEBSTER 57 (1988) (admix, “mingled”); <i>id.</i> (adixture, “something added by mixing”)</p> <p>4/27/2012 Dep. Tr. D. Reardon at 56:9 – 57:11 (JPIAM378456-57)</p> <p>5/1/2012 Dep. Tr. H. Cook at 28:10-18 (JPIAM378586)</p> <p>Defendants may rely on expert testimony.</p>
“the components are admixed sequentially” (’203 patent, claim 7)	No construction necessary.	<p>’203 patent at col. 8:43 to 8:47</p> <p>’203 patent file history</p> <p>Jazz may also rely on expert testimony.</p>	<p>Indefinite, but to the extent it may be construed:</p> <p>“the act of creating a mixture by adding components in succession without others coming in between”</p>	<p><u>Intrinsic Evidence</u></p> <p>’203 patent at col. 3, ll. 51-53; col. 8, ll. 43-47; col. 31, l. 5 – col. 32, l. 35 (Example 4)</p> <p><u>Extrinsic Evidence</u></p> <p>NINTH NEW</p>

Term (Patent Claims)	Jazz's Proposed Definition	Jazz's Evidence	Defendants' Proposed Definition	Defendants' Evidence
				<p>COLLEGiate DICTIONARY – MERRIAM WEBSTER 57 (1988) (admix, “mingled”); <i>id.</i> (adixture, “something added by mixing”); <i>id.</i> at 1074 (sequential, “following in sequence”)</p> <p>4/27/2012 Dep. Tr. D. Reardon at 56:9 – 57:11 (JPIAM378456-57)</p> <p>5/1/2012 Dep. Tr. H. Cook at 28:10-18 (JPIAM378586)</p>
<p>“the components are admixed simultaneously” (’203 patent, claim 8)</p>	<p>No construction necessary.</p>	<p>‘203 patent at col. 8:43 to 8:47</p> <p>‘203 patent file history</p> <p>Jazz may also rely on expert testimony.</p>	<p>Indefinite, but to the extent it may be construed:</p> <p>“the act of creating a mixture by adding components at the same time”</p>	<p><u>Intrinsic Evidence</u></p> <p>‘203 patent at col. 3, ll. 51-53; col. 8, ll. 43-47; col. 31, l. 5 – col. 32, l. 35 (Example 4)</p> <p><u>Extrinsic Evidence</u></p> <p>NINTH NEW COLLEGiate DICTIONARY – MERRIAM WEBSTER 57</p>

Term (Patent Claims)	Jazz's Proposed Definition	Jazz's Evidence	Defendants' Proposed Definition	Defendants' Evidence
				(1988) (admix, “mingled”); <i>id.</i> (admxiture, “something added by mixing”); <i>id.</i> at 1099 (simultaneous, “existing or occurring at the same time”) 4/27/2012 Dep. Tr. D. Reardon at 56:9 – 57:11 (JPIAM378456-57) 5/1/2012 Dep. Tr. H. Cook at 28:10-18 (JPIAM378586) Defendants may rely on expert testimony.
“an aqueous composition comprising a first dose . . . and an aqueous composition comprising a second dose” ('506 patent claim 1; ‘062 patent, claims 1, 8)	No construction necessary.	‘506 patent at col. 9:22- 34; 25:45-52; 26:18-20. ‘506 patent file history, including 4/2/2009 Response at 33-35; 1/11/2010 Response at 5-7. McGraw-Hill Dictionary of Scientific and Technical Terms (5th ed.) at 605.	“an aqueous composition as orally administered to the patient as a first dose . . . and an aqueous composition as orally administered to the patient as a second dose”	<u>Intrinsic Evidence</u> ‘506 patent; col. 2, l. 67 – col. 3, l. 3; col. 8, l. 65 – col. 9, l. 19; col. 9, ll. 50-56, l. 66 to col. 10, l. 33; col. 12, ll. 53-65; col. 15, ll. 6-26, 51-66; col. 17, ll. 36-40; col. 18, ll. 29-67; col. 19, ll. 6-8; col. 25, ll. 48-51; col. 27, ll. 31-32; col. 28, l. 65 – col. 29, l. 7;

Term (Patent Claims)	Jazz's Proposed Definition	Jazz's Evidence	Defendants' Proposed Definition	Defendants' Evidence
		<p>Merriam Webster's Collegiate Dictionary (10th ed.) at 346.</p> <p>Stedman's Medical Dictionary (26th Ed. 1995) at 517.</p> <p>Jazz may also rely on expert testimony.</p>		<p>col. 30, ll. 10-11; col. 72, ll. 19-33 (AMNXYR_000006879 – AMNXYR_000006920)</p> <p>'062 patent; col. 3, ll. 3-6; col. 9, ll. 2-28, 54-60; col. 10, ll. 3-39; col. 12, ll. 55-67; col. 15, ll. 8-30; col. 15, l. 54 – col. 16, l. 2; col. 17, ll. 41-48; col. 18, ll. 26-44, 48-52; col. 25, ll. 15-21; col. 26, ll. 62-63; col. 28, ll. 29-38; col. 29, ll. 41-42 (JPIAM363981 – JPIAM_364020)</p> <p>'275 patent; col. 72, ll. 10-45 (AMNXYR_000006987 – AMNXYR_000007027)</p> <p>Prosecution History of the '506 patent, including, but not limited to, claim 1 as filed, p. 101;</p>

Term (Patent Claims)	Jazz's Proposed Definition	Jazz's Evidence	Defendants' Proposed Definition	Defendants' Evidence
				<p>Amendment and Response filed April 6, 2009, in particular, pp. 29-30; Amendment and Response filed July 28, 2010, in particular, pp. 2 and 4; Notice of Allowance mailed October 8, 2010, in particular, Notice of Allowability at p. 2 (AMNXYR_00011263-AMNXYR_000012256, including, but not limited to, AMNXYR_000011266, AMNXYR_000012072</p> <p>—</p> <p>AMNXYR_000012114, AMNXYR_000012195</p> <p>—</p> <p>AMNXYR_000012204, AMNXYR_000012213</p> <p>—</p> <p>AMNXYR_000012219)</p> <p>Prosecution History of the '275 patent, including, but not limited to, Amendment and Response filed</p>

Term (Patent Claims)	Jazz's Proposed Definition	Jazz's Evidence	Defendants' Proposed Definition	Defendants' Evidence
				<p>August 24, 2012, in particular, pp. 5-6 (AMNXYR_000013415 – AMNXYR_000014142, including, but not limited to, AMNXYR_000013639 – AMNXYR_000013651)</p> <p>Prosecution History of the '431 patent, including, but not limited to, claim 56 as filed, p. 111 (AMNXYR_000018210 – AMNXYR_000018528, including, but not limited to, AMNXYR_000018340)</p> <p>Prosecution History of U.S. Patent Application No. 12/913,644, including, but not limited to, Preliminary Amendment dated January 10, 2011, in particular, pp. 31-32</p>

Term (Patent Claims)	Jazz's Proposed Definition	Jazz's Evidence	Defendants' Proposed Definition	Defendants' Evidence
				(AMNXYR_0100536 – AMNXYR_0100864) <u>Extrinsic Evidence</u> Webster's Ninth New Collegiate Dictionary (1991) (AMNXYR_000018861 – AMNXYR_000018866) Defendants may rely on expert testimony.
“greater than about 500 mg/mL” ('506 patent, claim 1)	No construction necessary.	‘506 patent at col. 3:46 – 3:47; col. 4:31 – 4:32; col. 11:10 – 12:23; col. 19:34 – 19:51 ‘506 patent file history	“greater than 500 mg/mL”	Defendants may rely on expert testimony.
“wherein the composition has a pH of about 8.0” / “of about 8.5” ('650 patent, claims 3, 4)	No construction necessary.	‘650 patent at col. 3:65 – 4:14; col. 4:46 – 5:3; col. 5:4 – 5:40 ‘650 patent file history Jazz may also rely on expert testimony.	“wherein the composition has a pH of 7.95 to 8.04” “wherein the composition has a pH of 8.45-8.54”	<u>Intrinsic Evidence</u> '650 patent, col. 5, ll. 65 to col. 4, ll. 14 Defendants may rely on expert testimony.

Exhibit A**Disputed Claim Terms****'306 PATENT FAMILY**

Term (Patent Claims)	Jazz's Proposed Definition	Jazz's Evidence	Defendants' Proposed Definition	Defendants' Evidence
“administering” (‘306 patent, claims 1, 6, 11, 17, 19, 25, 27, 30, 33; ’302 patent, claims 1, 13, 20, 27, 31)	No construction necessary.	<p>‘306 patent at col. 1:24 – 5:20; col. 9:5 – 9:7; col. 11:13 – 11:21; col. 18:18:38 – 18:47; col. 19:59 – 19:63</p> <p>Random House Dictionary of the English Language (2nd ed.); Cambridge International Dictionary of English; Clinical Trials Dictionary</p> <p>‘306 patent file history;</p> <p>‘302 patent file history</p> <p>Jazz may also rely on expert testimony.</p>	“to give or apply”	<p><u>Extrinsic Evidence</u></p> <p>Webster’s New World College Dictionary, 4th ed. (1999): [administer] “to give or apply (medicine, etc.)”</p> <p>Defendants may rely on expert testimony.</p>

Term (Patent Claims)	Jazz's Proposed Definition	Jazz's Evidence	Defendants' Proposed Definition	Defendants' Evidence
“also being administered” ('306 patent, claims 19, 30, 33)	No construction necessary.	<p>‘306 patent at col. 3:22 – 3:30; 3:31 – 3:41; 3:42 – 3:52</p> <p>‘306 patent file history</p> <p>Jazz may also rely on expert testimony.</p>	“the administration of a drug to a patient within a time period during which the effects of a previously administered dose of the drug is still operative in the patient”	<p><u>Intrinsic Evidence</u></p> <p>’306 patent; col. 1, ll. 15-20; col. 1, ll. 24-32; col. 1, l. 65 – col. 2, l. 9; col. 2, ll. 16-19; col. 2, l. 55 – col. 3, l. 54, col. 5, ll. 16-29; col. 8, ll. 37-41; col. 9, ll. 23-26; col. 10, ll. 33-39; col. 10, l. 47 – col. 11, l. 20; col. 18, ll. 28-53; col. 19, ll. 55-67; col. 20, l. 10 – col. 24, l. 6</p> <p>Prosecution History of the ’306 patent, including but not limited to: (1) Applicant’s Nov. 13, 2013 Response to Notice of Non-Compliant Amendment (37 CFR 1.21) and Supplemental Amendment and Response Under 37 C.F.R. § 1.111; and (2) the Dec. 19, 2013 Notice of Allowability.</p>

Term (Patent Claims)	Jazz's Proposed Definition	Jazz's Evidence	Defendants' Proposed Definition	Defendants' Evidence
				Defendants may rely on expert testimony.
"currently taking" ('302 patent, claims 1, 8, 13, 20, 21, 22, 26, 27, 31)	No construction necessary.	'302 patent at col. 2:63 – 3:4 '302 patent file history Jazz may also rely on expert testimony.	"the administration of a drug to a patient within a time period during which the effects of a previous dose of the drug is still operative in the patient"	<u>Intrinsic Evidence</u> '302 patent; col. 1, ll. 13-18; col. 1, ll. 22-30; col. 1, l. 64 – col. 2, l. 8; col. 2, ll. 14-17; col. 2, l. 53 – col. 3, l. 50; col. 8, ll. 37-41; col. 9, ll. 23-26; col. 10, ll. 33-39; col. 10, l. 47 – col. 11, l. 20; col. 18, ll. 28-53; col. 19, ll. 55-67; col. 20, l. 10 – col. 24, l. 6 Prosecution History of the '302 patent, including but not limited to Applicant's Sep. 15, 2014 Amendment Under 37 C.F.R. § 1.111 Defendants may rely on expert testimony.